REMARKS

The Examiner feels that a basic problem with the present application is a failure to teach how an assay resource can be initially configured so as to have excess capacity. Applicant believes that such a teaching is common knowledge in the field of designing automated clinical instrumentation devices and provides herewith an Affidavit under 37 CFR 1.132 to this effect.

Specification Objections –35 USC §132(a), first paragraph

The amendment filed December 28, 2006 is objected to because it is believed by the Examiner to introduce new matter into the disclosure. Substitute paragraphs [0023], [0027], [0029] and [0030] are provided above in which all material added December 28, 2006 is removed in view of the Examiner's requirement. However, additions to [0027], [0029] and [0030] are requested that are believed to be fully supported by the last sentence of originally filed paragraph [0030] or in originally filed Claim 6 or in the Abstract.

In particular:

- Re additions to paragraph [0023], the supporting, relevant portion of the application is found in original [0030] which reads, "It is important in such teaching that analyzer 10 be originally designed and configured so that space and other assay operational devices, for instance incoming and outgoing sample tube transport system 36 like seen in FIG. 5, are also initially adapted to accommodate the addition of throughput limiting resources.", and in original Claim 6 which reads, "the analyzer is further initially configured such that the operating resources which are not throughput limiting are also initially adapted to accommodate the addition of throughput limiting resources."; and,

- Re additions to paragraphs [0027], [0029] and [0030], the supporting, relevant portion of the application is found in original Claim 6 which reads, "the analyzer is further initially configured such that the operating resources which are not throughput limiting are also initially adapted to accommodate the addition of throughput limiting resources."

It is therefore respectfully requested that the objection under 37 CFR 1.114 be withdrawn.

Claim Rejections –35 USC §112, first paragraph

Claims 3-5 and 7 are rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. The Examiner raises a number of questions under this objection and applicants will address them as best understood and in the order found in the Office action dated March 14, 2007

The present method for increasing analyzer throughput begins with an analyzer initially configured with two reagent probes, 60P1 and 60P2, translatable between a single reagent storage area 26 and cuvette ports 20 and less than all of the available cuvette ports 20 filled with a reaction cuvette 24.

In Item 4, page 2 of the Office action dated March 14, 2007, the Examiner correctly understands that, "the reagent addition resources are initially throughput limiting and the other assay resources are capable of handling more assay throughput." However, the Examiner then concludes, "This places a requirement that these other assay resources be provided in such a manner that they can interact with the additional reagent resources to increase the throughput." This is an inaccurate conclusion because the "other assay resources" do not "interact with the additional reagent resources" in the manner implied by the Examiner. The "other assay resources" are

"assay operational devices 13, such as sensors, reagent add stations, mixing stations and the like that operate as needed on an assay mixture contained within cuvettes 24 and reaction vessels 25" (para [0020]).

Thus, the specification teaches that these "other assay resources" continue to operate on samples or cuvettes in the same manner as they operated in the initial analyzer configuration except they are operating at a higher throughput rate. This is straightforwardly possible because the analyzer is initially with these "other assay resources" being not throughput limiting as explained in originally filed claim 6. When an additional reagent server resource is added to the analyzer, the other assay operational devices simply "operate as needed" on a greater number of incoming sample racks 42 (in the case of sample tube transport system 36) or they "operate as needed" on a greater number of sample-reagent mixtures in reaction cuvettes 24 in the case of "assay operational devices 13, such as sensors, reagent add stations, mixing stations and the like . . . on an assay mixture contained within cuvettes 24" as explained in the last sentence of paragraph [0019].

The Examiner next considers a hypothetical single reagent assay and states that "applicant has not provided an explanation of how the sample dispenser and washing mechanism are not throughput limiting" (line 7, page 3 of the instant Office Action). The Examiner has acknowledged that, "the other assay resources are capable of handling more assay throughput." As an example, the sample dispensing and washing mechanisms are initially configured with the capacity to "operate as needed" on, say 1000 reaction cuvettes per hour. Given the teaching of the present invention, configuring an assay operational device to have an initial higher throughput and then to operate at a lower throughput is well within the ability of an artesian as declared in the attached Affidavit under 37 CFR 1.132.

The Examine then references end-point and rate type assays and concludes, "different assays place different requirements on a system and applicant has not

described how the additional resources can be configured to meet these varied needs even for a single reagent assay." This concern is not clearly understood; it is appreciated that the analyzer is initially configured with two types of resources as required to perform a certain menu of assays:

i. One throughput limiting assay resource – reagent supply, in particular, and
ii. Non-throughput assay resources – sample add, wash, mix, read and the like.

Certainly different assays have different minimum times in which to be completed, but they simply stay on reaction carousel 14 for a longer of time. However, applicant is not adding reagent resources so that only a different menu of assays can be performed. As described in the Summary of the Invention, paragraph [0010],

> The task of increasing the analyzer's throughput as the clinical laboratory's test load increases is achieved by providing the analyzer with an initial throughput level in which the capacity for conducting assays is limited by the capacity of an operational resource like a reagent resource. If and when the clinical laboratory's test load increases beyond the initial throughput level, additional throughput capacity for conducting assays is achieved by incrementally adding additional operational resource like a reagent resource so as to provide additional assay reagents. (Underlining added for emphasis)

Applicant's invention thus teaches a method for increasing throughput when the test load increases . . . and not merely increasing the scope of the assay menu the analyzer is capable of performing. Thus, incrementally increasing throughput by increasing reagent resources only requires that a wash station (for example) that is initially configured with the capacity to "operate as needed" on say 1000 reaction

cuvettes per hour can clearly operate on fewer than 1000 cuvettes per hour when the throughput is limited to a single reagent resource.

The Examiner states, "the invention is much more complex than adding reagent resources and applicant has not provided an enabling disclosure." As explained above and to the contrary, the invention comprises initially configuring an analyzer with reagent resources that limit the throughput of the analyzer and at the same time, initially configuring the analyzer such that, as the Examiner recognizes, "the other assay resources are capable of handling more assay throughput." Applicant thus believes the disclosure is enabling and herewith presents an Affidavit under 37 CFR 1.132 to this effect.

The Examiner further states, "While original paragraph [0030] states that the full number of cuvette ports is under utilized and the original abstract would seem to point to the number that are not available before the addition of additional reagent resources is 50%, there is no description of how the device is configured so that this is the case." It is well within the ability of one skilled in the art to initially configure an analyzer with a number of cuvette ports 20 and then to underutilize them, for example as illustrated in FIG. 2, wherein only one cuvette 24 is shown as disposed in the nine cuvette ports 20.

Next, the Examiner considers the data in Tables 1, 2 and 3 and concludes that, "the application fails to teach how to increase the capacity to reach a throughput of more than 1000 assays/hour by adding reagent resources in an incremental manner".

Applicants point out that Tables 1, 2 and 3 are illustrations of the general principle taught in paragraph [0027], that whatever operating resources are throughput limiting, in this case reagent resources, those resources can be incrementally added as the incoming assay demand increases, and the throughput of analyzer is proportional to the number of additional reagent storage areas. Each of the Tables addresses an instance wherein, say for Table 1, when analyzer 10 is reagent resource limited, then when analyzer 10 must access server 26 more than one time, as in the instance of assays

requiring two or three reagents, then additional time is required to process such assays and the throughput decreases accordingly.

Tables 2 and 3 simply illustrate that, when two or three reagent servers are available to be used by analyzer 10, then, in the instance of assays requiring two or three reagents, two or three of the newly available reagent servers may be accessed at the same time, and although the throughput of the three reagent assays will be lower than that for the two reagent assays, throughput is correspondingly increased above that achieved with only one reagent server installed. The Examiner is trying to limit Tables 1, 2 and 3 to one exemplary embodiment of the present invention wherein 50% of the initial cuvette ports 20 are loaded with cuvettes 24 and this is not in accord with the as-claimed invention. What is important is that the throughput of all three types of assays is increased as additional reagent resources are added, regardless of the type of assay. In reality, the assays to be conducted by analyzer 10 would generally be a mix of the three types of assays. In this case, as shown in [0027], throughput T is inversely proportional to the Average number A of reagent additions per assay. However, the Examiner then determines to examine the claims as covering (1) the ability to perform new assays, or (2) the addition of capacity to add multiple reagents simultaneously.

Concerning instance (1), paragraph [0010] cited above make it clear that Applicant's invention comprises a method for increasing throughput when the test load increases . . . and not merely increasing the assay scope of the test menu the analyzer is capable of performing. In this instance (1), discussed below, the present case stands rejected as anticipated by a reference that teaches the addition of resources to perform different assays, as is not the case with Applicant's invention. Concerning instance (2), Tables 2 and 3 make it clear that multiple reagents are indeed accessed simultaneously from servers 26, 27 and 28

In view of all of the above reasons, it is believed that the specification is fully enabling and respectfully requests the withdrawal of the rejection under 35 USC 112, first paragraph.

Claim Rejections –35 USC §112, second paragraph

Claims 3-5 and 7 are rejected under 35 USC 112, second paragraph, as being indefinite. The Examiner finds it to be not clear that the "initially configured reagent resource (server 26), contains all of the reagents to perform all of the assays in the group or if only a portion is necessary to meet the claim." Claim 7 straightforwardly that the present invention requires "initially configuring the analyzer with reagent resources to conduct a group of assays" and this should be interpreted on its face as containing all of the reagents to perform all of the assays in the group.

It is not understood why the Examiner would treat the claims as "not requiring the initial reagent resources to contain all of the reagents necessary to perform the assays of the group" . . . because this would mean that the analyzer was unable to perform some of the assays in its menu of assays. If this had been the intent of the instant application, the claims and specification would be directed at increasing the type or menu of assays an analyzer could perform. In contrast, the instant application, the claims and specification are directed at increasing the throughput of assays an analyzer can perform. In view of the amendment to claim 7, which makes clear that the analyzer is initially configured with all of the reagents necessary for conducting a certain group of assays, it is requested that the rejection under 35 USC 112, second paragraph be withdrawn.

Claim Rejections –35 USC §102(b)

Claims 3-5 and 7 are rejected under 35 USC 102(b) as being anticipated by Jones (US 3,615,239). The Examiner cites Jones for teaching that the number of

diagnostic tests to be performed by the analyzer may be increased by adding a further module. Jones is attempting to solve the problem of analyzer's only being able to perform a single type of diagnostic test (Col. 1, lines 26-29) and does this by increasing the number of treatment stations 26-30 so as to accommodate more than one type of diagnostic test (Col. 2, lines 13-17). Thus, in the instance of Jones, each module is designed to implement a different assay and additional modules are added in order to add a new different assay to the analyzer's menu. As specified, Jones' analyzer is intended for use when a substantial number of different tests may be performed (Col. 1, lines 44-46) and that this may be accomplished by his invention since, "the programmer includes a plurality of modules, each being representative of the treatment required for a different diagnostic test."(Col. 2, lines 63-65) Further, as the Examiner stated, "In the apparatus disclosed, five treatment stations are indicated although a greater or smaller number may be provided depending on the number and type of different diagnostic tests to be performed."

Thus, Jones' modular programming disk has the effect of adding different assays to the analyzer's menu and does not increase throughput of the analyzer as does Applicant's claimed invention. As stated previously concerning instance (1), paragraph [0010] cited above make it clear that Applicant's invention comprises a method for increasing throughput when the test load increases . . . and not increasing the scope of the test menu the analyzer is capable of performing.

Since Jones does not expressly or inherently disclose the claimed step of initially configuring the analyzer with reagent resources that are throughput limiting in conducting a certain group of assays, Jones cannot be said to anticipate the present invention and Applicant respectfully requests that the rejection over Jones be withdrawn.

Claim Rejections –35 USC §103(a)

Claims 1-5 are rejected under 35 USC 103(a) as unpatentable over Berglund (US 4,459,265) or Minekane (US 4,906,433) in view of Jones (US 3,615,239). Berglund discloses an analyzer wherein the number of reagent-supply stations and their location may be varied to suit different purposes. The Examiner recognizes that, "Berglund does not teach modular configuration for the additional reagent-supply stations." Minekane's teachings are similar to Berglund's, in that Col. 7 lines 35-45 disclose reagent containers that may be positioned on different arcs, however, as the Examiner noted, "Minekane does not teach a modular configuration for the additional reagent storage locations."

As discussed above, Jones does not disclose the step of initially configuring the analyzer with reagent resources that are throughput limiting in conducting a certain group of assays. Thus the combination of Berglund and/or Minekane and Jones fails to make Applicant's invention unpatentable because no modification of the references teaches or even suggests initially configuring an analyzer with reagent resources that are throughput limiting for conducting a certain group of assays and at the same time configuring the analyzer with all other assay resources that are not throughput limiting for conducting the same assays. Applicant also claims incrementally adding reagent resources to the analyzer in order to increase throughput as the number of assays within the same, certain group of assays to be conducted increases and this feature cannot be replicated by any combination of the teachings of Berglund and/or Minekane and Jones. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness and it is requested that the rejection over Berglund or Minekane in view of Jones be withdrawn.

In response to Applicant's arguments filed December 28, 2006, the Examiner says, "The basic problem with the instant application is that while it does make the

statement that the other assays resources are under utilized, it does not teach how these other resources are configured so that they have excess capacity and how the instrument is configured to utilize that excess capacity with the addition of the additional reagent resources." (page 8 of the Office Action dated March 14, 2007).Firstly, this is well within the level of skill in the art as explained in the attached Affidavit, and secondly, this is not the subject matter of the claimed invention. The claimed invention only requires that the analyzer be initially configured with reagent resources that are throughput limiting and all other assay resources being not throughput limiting. That is, the only requirement claimed for the "all other resources" is that they are not throughput limiting. Similarly, the instant claims do not need to "define reasons for the increased capacity" as the Examiner seems to require.

Applicants firmly believe that a skilled clinical analyzer design engineer, being informed that not all of the available cuvette ports are being used when only a single reagent server is available ([0030] above), would immediately recognize the necessity to supply addition cuvettes into the available cuvette ports when a second reagent server was installed to add throughput.

Applicants further believe that a skilled clinical analyzer design engineer, being informed that "the analyzer is further initially configured such that the operating resources which are not throughput limiting are also initially adapted to accommodate the addition of throughput limiting resources", and provided with specific reference to the sample transport system 50 and attention called to FIG. 5, would immediately understand that the "other assay resources requires to conduct an assay" were underutilized in the initial configuration of analyzer 10 (with only one reagent resource) and that their usage (or throughput) increases as additional reagent resources are added.

To support Applicant's position, an Affidavit under 37 CFR 1.132 is provided herewith in which a degreed mechanical engineer, skilled in the art of designing of automated clinical instrumentation devices, declares that;

(1) from the description provided, one skilled in the art can initially configure an analyzer with assay resources such as wash stations, cuvette carousels carrying cuvette ports, sample add stations, sample transport systems and the like, at a high capacity or throughput level, and then operate the analyzer at lower capacity or throughput levels; and,

(2) that the patent disclosure identified above would fully enable one skilled in the art to increase the throughput of a clinical analyzer, as claimed, by:

- initially configuring the analyzer with reagent resources to conduct a group of assays, these reagent resources being throughput limiting;
- initially configuring the analyzer with all other assay resources required to conduct said group of assays, the other assay resources not being throughput limiting; and,
- incrementally adding reagent resources to the analyzer in order to increase throughput as the number of assays within the group of assays to be conducted increases.

Applicant thus believes that this application contains patentable subject matter and that the foregoing amendments provide a basis for favorable consideration and allowance of all claims; such allowance is respectfully requested.

Respectfully submitted,

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